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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/321,766	05/28/1999	AWADHESH K. MISHRA	121-176	7018

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/23/2002 18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 69/321766	Applicant(s) MISHRA	
Examiner WEBMAN	Group Art Unit 1617	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/10/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 21-62 is/are pending in the application.
- Of the above claim(s) 58, 58-62 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 21-54, 56, 57 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Applicant Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 15
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Newly submitted claims 55, 58-62 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: applicants originally claimed a composition, in particular a suspension. Now ^{he} additionally _^ claims a powder and a method of making.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55, 58-62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 38-54, 56-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a suspension without surfactants which have a tendency to coagulate on steam sterilization, does not reasonably provide enablement for a suspension with such surfactants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. On page 2, last paragraph bridging to page 3 applicants disclose suspensions absent these surfactants. ~~No~~ other suspensions are specified..

Claims 48, 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 48, 56 "suitable" is vague; under what conditions?

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Claims 21-38, 40-54, 56, 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 21, 22, 38 "substantially" is vague; what percent? It can mean as high as 49%. *E.W. Bliss v. Cold Metal Process Co.* (DC N OHIO) 122 USPQ 238.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-54, 56, 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyata et al in view of Muller et al.

Muller et al teach a nanosuspension comprising 0.001-30% lecithin (claims 1, 13, 15), the compound polyvinyl alcohol, poloxamer glucose, mannose, trehalose and sorbitol at 0.1-2% (claims 1-22) and 0.1-30% active (claims 1, 7). Parental, intramuscular, and subcutaneous administration are disclosed (column 6, line 61, column 9, line 33). Antimycotic, corticoid, and immuno therapeutics such as cyclosporin are specified (claims 39, 48). Autoclaving is disclosed (figures 13, 14).

Miyata et al teach autoclaving a suspension under nitrogen (column 9, lines 31-38) to maintain a composition stable to oxidation (column 9, line 64-column 10, line 2).

It would have been obvious to one of ordinary skill to improve the stability of the Muller et al suspension by autoclaving under nitrogen in view of Miyata et al.

Claims 38-54, 56, 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for phospholipid surface modifier, does not reasonably provide enablement for any surface modifier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. On page 4, the penultimate paragraph, phospholipids are specified. No other surface modifier is disclosed.

Claims 38-54, 56, 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the amount of modifier and thermoprotectant in relation to the amount and size of particles, does not reasonably provide enablement for any amount of thermoprotectant and any amount of particles in claims 21, 22, 38, 39 and any amount of modifier and any particle size in claims 38, 39. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To avoid coagulation, it is argued that sufficient amounts of modifier and thermoprotectant must be present relative to the amount and size of suspended particles. However, applicants do not claim all these parameters.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday 9am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins can be reached on 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 305-3592 for regular communications and 305-1235 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Webman:mv
August 30, 2002

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500